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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,209	06/02/2006	Nanping Zhong	8378/88501	3439
22342 7590 04/06/2009 FITCH EVEN TABIN AND FLANNERY 120 SOUTH LASALLE STREET SUITE 1600 CHICAGO, IL 60603-3406				
EXAMINER				
DAVIS, ZINNA NORTINGTON				
ART UNIT		PAPER NUMBER		
1625				
MAIL DATE		DELIVERY MODE		
04/06/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/596,209

Applicant(s)

ZHONG ET AL.

Examiner

Zinna Northington Davis

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

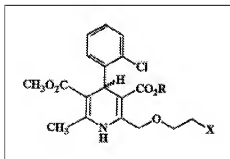
- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S509)
Paper No(s)/Mail Date 06/02/06, 01/31/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

1. Claims 1-12 are pending.
2. At page 1 of the specification, the continuing data should be updated.
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfizer Limited (Reference 1, cited by Applicants) in view of U. S. Department of Health and Human Service (Reference U, cited by the Examiner).

Reference 1, cited by Applicants, teaches a process for obtaining a racemic amlodipine with D- or L- tartaric acid and dimethyl sulfoxide (DMSO) as the organic solvent. See the entire document. The instantly claimed compound is disclosed as follows:



wherein R is-CH₂CH₃ and X is NH₂. The difference

between the instantly claimed process and the prior art process is the use of the solvent, DMSO versus 2-butanone.

Reference U, cited by the examiner, is largely cumulative of the reference cited in the specification, Guidance for Industry **IMPURITIES: RESIDUAL SOLVENTS**, FDA, May 15, 2001). Reference U teaches a list of solvents used in the industry and the guidance for usage. At page 7, Table 3, Class 3 solvents are used in pharmaceutical products because of their inherent toxicity. The Class 3 solvents are regarded as less toxic and of lower risk to human health hazard. DMSO and 2-butanone are class 3 solvents.

It would have been obvious to one of ordinary skill in the art to replace one Class 3 solvent of the prior art with another Class 3 solvent as instantly claimed. Based upon the teaching of the Class 3 solvent in a pharmaceutical product such as amlodipine, there is motivation to interchange one class of solvent for another in view of the similar process for preparation. Accordingly, the claims are unpatentable therefrom.

5. Reference N (cited by the Examiner) is the English translation of Reference 1.
6. The Information Disclosure Statements filed June 2, 2006 and January 31, 2008 have been considered.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682. The examiner can normally be reached on M-F.
8. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zinna Northington Davis/
Zinna Northington Davis
Primary Examiner
Art Unit 1625